

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

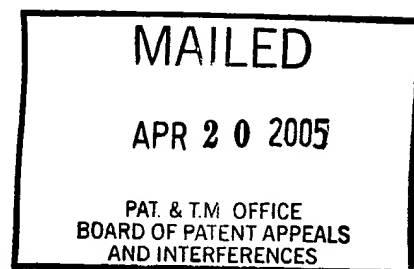
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte EUGENE D. THORSETT, CHRISTOPHER M. SEMKO, MICHAEL A. PLEISS,
ANDREI W. KONRADI, FRANCINE S. GRANT, DARREN B. DRESSEN,
and REINHARDT BERNHARD BAUDY

Appeal No. 2005-0907
Application No. 09/126,096

ON BRIEF



Before ELLIS, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-4, 7, 10, 12, 13, and 15-22, all of the claims remaining. Claim 22 is representative and reads as follows:

22. A compound selected from the group consisting of:

N-(toluene-4-sulfonyl)-L- α -methylprolyl-L-phenylalanine;

N-(toluene-4-sulfonyl)-L- α -methylprolyl-L-4-(isonicotinamido)phenylalanine
methyl ester;

N-(toluene-4-sulfonyl)-L- α -methylprolyl-L-4- (isonicotinamido)phenylalanine;

N-(toluene-4-sulfonyl)- α -methylprolyl-L-4-(1-methylpiperidin-4-oxy)
phenylalanine ethyl ester;

N-(toluene-4-sulfonyl)- α -methylprolyl-L-4-(1-methylpiperidin-4-oxy)
phenylalanine;

N-(toluene-4-sulfonyl)- α -methylprolyl-L-4-(4-methylpiperazin-1-
carbonyloxy)phenyl-alanine *tert*-butyl ester;

N-(toluene-4-sulfonyl)- α -methylprolyl-L-4-(*N,N*-dimethylcarbamyloxy)
phenylalanine *tert*-butyl ester;

N-(toluene-4-sulfonyl)- α -methylprolyl-L-4-(4-methylpiperazin-1-
carbonyloxy)phenyl-alanine;

N-(toluene-4-sulfonyl)- α -methylprolyl-L-tyrosine *tert*-butyl ester;

N-(toluene-4-sulfonyl)- α -methylprolyl-L-4-(*N,N*-dimethylcarbamyloxy)
phenylalanine;

N-(toluene-4-sulfonyl)- α -methylprolyl-L-4-(morpholin-4-ylcarbonyloxy)
phenyl-alanine *tert*-butyl ester;

N-(toluene-4-sulfonyl)- α -methylprolyl-L-4-(morpholin-4-ylcarbonyloxy)
phenyl-alanine;

N-(toluene-4-sulfonyl)- α -methylprolyl-D-tyrosine *tert*-butyl ester;

N-(toluene-4-sulfonyl)- α -methylprolyl-L-4-(morpholin-4-ylcarbonyloxy)
phenyl-alanine 1-(trimethyacetoxymethyl) ester;

N-(toluene-4-sulfonyl)- α -methylprolyl-L-4-[*N*-(2-(*N'*,*N'*-dimethylamino)ethyl)-
N-methylcarbamyloxy]phenylalanine *tert*-butyl ester;

N-(toluene-4-sulfonyl)- α -methylprolyl-L-4-[*N*-(2-(*N'*,*N'*-dimethylamino)ethyl)-
N-methylcarbamyloxy]phenylalanine;

N-(4-fluorobenzenesulfonyl)- α -methylprolyl-L-4-(*N,N*-dimethylcarbamyloxy)
phenylalanine *tert*-butyl ester;

N-(4-fluorobenzenesulfonyl)- α -methylprolyl-L-4-(*N,N*-dimethylcarbamyloxy)
phenyl-alanine

or pharmaceutically acceptable salts thereof or any of the ester compounds recited above wherein one ester group is replaced with another ester group selected from the group consisting of methyl ester, ethyl ester, *n*-propyl ester, isopropyl ester, *n*-butyl ester, isobutyl ester, *sec*-butyl ester and *tert*-butyl ester.

The examiner relies on the following reference:

Thorsett et al. (Thorsett)

6,492,421

Dec. 10, 2002

Claims 1-4, 7, 10, 12, 13, and 15-22 stand rejected for obviousness-type double patenting in view of claims 1-35 of the '421 patent.¹

We affirm.

Discussion

The claims are directed to a genus of compounds defined by a chemical formula, specific compounds within the genus, pharmaceutical compositions, and methods of treating inflammatory diseases. Following a restriction requirement and an election-of-species requirement, the examiner noted that the "application has been examined to the extent readable on the elected invention, i.e., compounds of formula I or IA wherein R² and R³ together with the nitrogen and carbon to which they are attached, form a pyrrolidine ring." Paper No. 12 (mailed September 28, 2000), page 3.

The examiner rejected the claims based on the doctrine of obviousness-type double patenting. The examiner's analysis focused on one of the compounds recited in claim 22; specifically, N-(toluene-4-sulfonyl)- α -methylprolyl-L-4-(1-methylpiperidin-4-

¹ The Examiner's Answer actually says that claims "1-4, 6-7, 10 and 12-18 are rejected" but this appears to be a typographical error, in that claims 6 and 14-18 were not pending at the time the Examiner's Answer was written. In addition, the Office action mailed Feb. 4, 2003 applied the rejection to claims "1-4, 7, 10, 12, 13 and 15-22," the Appeal Brief presented the issue on appeal as "whether Claims 1-4, 7, 10, 12, 13 and 15-22 are unpatentable" (page 3), and the examiner stated that "[t]he appellant's statement of the

oxy)phenylalanine. The examiner pointed to claim 10 of the '421 patent, which is directed to, among other things, "N-(toluene-4-sulfonyl)-L-prolyl-4-(1-methylpiperidin-4-oxy)-D,L-phenylalanine." See the Examiner's Answer, pages 4-5. The examiner noted that the compound of the instant claims differs from that claimed in the '421 patent only by the presence of a methyl group; i.e., the instantly claimed compound has a methylprolyl substituent in the same position that the patented compound has a prolyl substituent, but the compounds are otherwise identical.

The examiner also noted that the claims of the '421 patent make clear that pharmaceutical compositions comprising, for example, N-(toluene-4-sulfonyl)- α -L-prolyl-L-4-(1-methylpiperidin-4-oxy)phenylalanine are useful in treating disease. Examiner's Answer, page 4. See the '421 patent's claim 11 (directed to a pharmaceutical composition), claim 22 (dependent on claim 11 and directed to a composition comprising, e.g., N-(toluene-4-sulfonyl)- α -L-prolyl-L-4-(1-methylpiperidin-4-oxy)phenylalanine (column 126, lines 25-26)), and claim 35 (directed to a method of treating disease using the composition of claim 11).

We agree with the examiner that the compound of the '421 patent's claim 10 would have made the instantly claimed compound prima facie obvious. "When chemical compounds have 'very close' structural similarities and similar utilities, without more a prima facie case may be made. See for example In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977) (adjacent homologs and structural isomers). . . . When such 'close' structural similarity to prior art compounds is shown, in accordance with these precedents

issues in the brief is correct" (Examiner's Answer, page 3). For these reasons, we conclude that the examiner intended the rejection to apply to all of the pending claims.

the burden of coming forward shifts to the applicant, and evidence affirmatively supporting unobviousness is required." In re Grabiak, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985). See also In re Jones, 958 F.2d 347, 349-50, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) ("Particular types or categories of structural similarity without more have, in past cases, given rise to prima facie obviousness; see, e.g., . . . In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977) (adjacent homologs and structural isomers).").

Thus, case law supports the examiner's position that a disclosed (or claimed) chemical compound suggests its adjacent homologs – i.e., similar compounds differing from the reference compound only by the presence or absence of a methyl substituent – and therefore renders those homologs prima facie obvious. The compound of instant claim 22 is an adjacent homolog of the compound of the '421 patent's claim 10 and therefore the two compounds are not patentably distinct.

Appellants argue that the examiner has not shown the presently claimed compound to be prima facie obvious because "[t]he Examiner has failed to explain why a skilled artisan would be motivated to substitute a non-naturally occurring α , α -disubstituted amino acid side chain for the naturally occurring α -substituted amino acid side chain. . . . The Examiner has failed to articulate why a skilled artisan would reasonably expect success from making such a substitution." Appeal Brief, pages 4-5.

This argument is not persuasive. As the case law cited above makes clear, where a claimed compound is nothing more than a homolog of a prior art compound, the prior art compound supports a prima facie case under § 103 without any particularized showing of a suggestion to modify the prior art compound. See In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979) ("An obviousness rejection based on

similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.”); In re Deuel, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995) (“Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties.”).

Here, the claimed compound is a homolog of the prior art compound, in that the claimed compound differs from the prior art compound only by the presence of a methyl group at a position occupied by a hydrogen atom in the prior art compound. Therefore, the structural relationship provides the requisite suggestion to modify the old compound because those of ordinary skill in the art would expect its homologs to have similar properties (e.g., to be useful in treating disease).

Appellants also argue that “[s]tructure alone does not dictate obviousness of chemical compounds” and “[h]omology alone does not determine patentability.” See the Appeal Brief, page 6 (headings).

These statements, while true, do not persuade us that the examiner’s rejection is in error. Structural similarity is sufficient to support a prima facie case of unpatentability under 35 U.S.C. § 103. “After a prima facie case of obviousness has been established, the burden of going forward shifts to the applicant. . . . If rebuttal evidence of adequate weight is produced, the holding of prima facie obviousness, being but a legal inference

from previously uncontradicted evidence, is dissipated." In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984).

In this case, for example, if Appellants had presented evidence that the instantly claimed compound has properties that differ unexpectedly from those of the compound of the '421 patent, such evidence would tend to rebut the case for obviousness based on structural similarity. Appellants have pointed to no such evidence and therefore the examiner's prima facie case stands unrebutted.²

Finally, Appellants argue that their position is supported by previous Board decisions,³ as well as decisions by the Court of Customs and Patent Appeals⁴ and the Court of Appeals for the Federal Circuit.⁵

This argument is not persuasive. All of the Board decisions and both of the CCPA decisions cited by Appellants predate In re Wilder, which held that the structural similarity shared by adjacent homologs, without more, supports a prima facie conclusion of obviousness. See Jones, 958 F.2d at 349, 21 USPQ2d at 1943: "Particular types or categories of structural similarity without more have, in past cases, given rise to prima facie obviousness; see, e.g., . . . In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977) (adjacent homologs and structural isomers)."

² We note that Appellants cite a reference by Salgado et al. that they characterize as "evidence of the non-equivalence between α -substituted amino acids and α,α -disubstituted amino acids." Appeal Brief, page 10. Appellants do not specify when the reference was submitted to the Office and entered into the record. We have reviewed the official Image File Wrapper of the present application but have not found any reference in the record authored by Salgado or Salgado et al. Therefore, this argument lacks an evidentiary basis in the record and, being unsupported by evidence, it is not persuasive.

³ Appellants rely on Ex parte Biel, 124 USPQ 109 (POBA 1958), Ex parte Goonewardene, 160 USPQ 287 (POBA 1968), and Ex parte Tilford, 121 USPQ 347 (POBA 1953).

⁴ Appellants rely on In re Coes, 173 F.2d 1012, 81 USPQ 369 (CCPA 1949), and In re Langer, 465 F.2d 896, 175 USPQ 169 (CCPA 1972).

⁵ Appellants rely on In re Lalu, 747 F.2d 703, 223 USPQ 1257 (Fed. Cir. 1984).

Obviously, that holding trumps any earlier Board decisions to the contrary. It also controls over any earlier CCPA decisions inconsistent with it. See In re Gosteli, 872 F.2d 1008, 1011, 10 USPQ2d 1614, 1617 (Fed. Cir. 1989) ("The CCPA's later decisions control because that court always sat en banc").

Appellants cite In re Lalu only for the proposition that "an obviousness analysis requires an inquiry as to whether anything in the prior art reference suggests the properties of the claimed compounds." Appeal Brief, page 8. Here, as discussed above, the compound claimed in the '421 patent suggests the properties to be expected for the compound now claimed, because those skilled in the art would expect such structurally similar compounds to have similar properties. See Payne, 606 F.2d at 313, 203 USPQ at 254 ("An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.").

Summary

The examiner's rejection is affirmed. We note, however, that the rejection can be overcome by a properly filed terminal disclaimer. That possibility seems to make this appeal something of an academic exercise. The instant application and the '421 patent both claim priority to applications that were filed on the same day (July 31, 1997). See the face of the '421 patent and, in the present application, the amendment received March 28, 2001 (page 1). Since both applications were filed after June 7, 1995, the terms of any patents issued is measured from the effective filing date. See 35 U.S.C. § 154.

Thus, the '421 patent and any patent issued based on the present application will both expire 20 years from July 31, 1997, and a terminal disclaimer would not shorten the term of a patent issuing from the present application by even one day. Apparently, the only practical effect of filing a terminal disclaimer to overcome the double patenting rejection is that Appellants would have to agree to keep the two patents commonly owned. See 37 CFR § 1.321(c)(3).

Since the rejection can be overcome with a terminal disclaimer and since the only practical effect of a disclaimer would be to require common ownership of the two patents, this appeal seems to be much ado over very little. Nonetheless, for the reasons discussed above, the rejection on appeal is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)(1)(iv)(effective September 13, 2004; 69 Fed. Reg. 49960 (August 12, 2004); 1286 Off. Gaz. Pat. and TM Office 21 (September 7, 2004)).

AFFIRMED



JOAN ELLIS
Administrative Patent Judge



DONALD E. ADAMS
Administrative Patent Judge



ERIC GRIMES
Administrative Patent Judge

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FOLEY & LARDNER, LLP
1530 PAGE MILL RD.
PALO ALTO, CA 93404

EBG/hh